UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,853	11/17/2000	Ashvin H. Desai	10284-0269451	8968

7590 06/06/2005

David H. Jaffer
Pillsbury Winthrop LLP
2550 Hanover Street
Palo Alto, CA 94304-1115

EXAMINER	
RAGONESE, ANDREA M	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

e

Office Action Summary	Application No.	Applicant(s)	
	09/715,853	DESAI, ASHVIN H.	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,15,17,20,21,24,25,33 and 37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,15,17,20,21,24,25,33 and 37-43* is/are rejected.

7)☒ Claim(s) *1,10,15,17,20,21,24,25,33 and 37-43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on February 14, 2005 has been entered. Examiner acknowledges that **claims 1, 20, 38** and **42** have been amended, **claims 2-9, 11-14, 16, 18, 19, 22, 23, 26-29, 31, 32** and **34-36** have been canceled and **claim 43** has been added. Subsequently, **claims 1, 10, 15, 17, 20, 21, 24, 25, 33** and **37-43** are under consideration.

Response to Arguments

2. Applicant's arguments, see page, filed February 14, 2005, with respect to the rejection of **claim 1** under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made hereinafter.

Terminal Disclaimer

3. The terminal disclaimer filed on February 14, 2005 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 6,461,296 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Drawings

4. The drawings are objected to because extraneous text should not be present in the drawings. Specifically, Figures 7-10 contain bulleted lists of text, in the form of tables, which are not acceptable forms of drawing figures. 37 CFR 1.58(a) permits tables, chemical and mathematical formulas in the specification. See MPEP § 608.01.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

> The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.
>
> The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The abstract of the disclosure is objected to because of the use of improper sentence structure. The abstract should only contain complete sentences, not sentence fragments as it currently does in the lines 1-2. Correction is required. See MPEP § 608.01(b).

Claim Objections

7. **Claims 1, 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are objected to because of the following informalities. Appropriate correction is required.

Regarding **claim 1**, the term "RF" should be spelled out in the claim the first time it appears.

Regarding **claim 15**, the comma "," should be deleted after "penetrated" in line 3.

Regarding **claim 21**, the term "BPH" should be spelled out in the claim the first time it appears; and the phrase "Transrectal, Transurethral and Transperineal approach" should be deleted and —transrectal, transurethral and transperineal approaches— should be inserted therefor.

Regarding **claim 30**, the terms "MRI" and "CT" should be spelled out in the claim the first time it appears.

Regarding **claim 37**, the term "chemo" should be deleted and —chemotherapy— inserted therefor.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **Claims 20, 38, 39, 42** and **43** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New matter is not permitted to be entered in an amendment. Specifically, the phrase "said substance conveyed in a ***non-metallic, bio-absorbable microsphere container***" is considered new matter since the original specification does not provide support for this claim limitation, and therefore, Applicant did not have possession of this particular invention at the time the instant application was filed.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. **Claims 1, 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, in **claims 1, 17** and **43**, Applicant recites "***said body***," "***said tissue***" and "***said target tissue***." These clauses (and other similar clauses) appear to positively recite a portion of the human body. Although the recitations of "said body" and "said tissue" are in inferential clauses, the use of "said" to refer to a body or body part raises the possibility that Applicant is positively reciting a body part a human being or a human being itself. Accordingly, **claims 1, 17** and **43** are considered to be directed to non-statutory subject matter. 1077 OG 24 (April 21, 1987). Dependent **claims 10, 15, 20,**

21, 24, 25, 30, 33 and **37-42** incorporate the non-statutory subject matter recited in the claims from which they depend. Applicant can overcome this rejection by reciting "***a/the*** body [or tissue/target tissue]."

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 1, 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US 5,472,441) in view of Roskos et al. (US 6,224,883 B1) and further in view of Mulier et al. (US 5,807,395).

Regarding **claim 1**, Edwards et al. discloses a method for treating a localized portion of body tissue via inserting a needle apparatus in a body, the apparatus including at least one hollow needle core for delivering an electrically conductive substance into the body in the form of a chemotherapeutic fluid, whereby the substance is limited to a localized portion of body tissue (column 7, lines 45-55; column 8, lines

55-65; column 9, lines 22-25; column 10, lines 1-15; column 13; column 16; column 17, lines 1-5; and column 18, lines 5-13). Further, Applicant is directed to column 16, lines 15-20 where the electrically conductive solution is discussed. Further, Edwards et al. recites guiding the needle apparatus to a desired volume tissue in need of treatment (column 6, lines 55-65 and column 7, lines 50-55), applying the substance to the volume of tissue through the needle apparatus, determining that the volume of tissue is penetrated by the substance (as discussed throughout the disclosure), and applying RF energy to the substance through an RF electrode to ablate the volume of tissue, where the substance serves an electrode extension conducting the RF energy throughout the volume (as recited throughout the disclosure with emphasis on columns 15-16).

However, Edwards et al. do not explicitly recite a non-invasive imaging technique for guiding the needle or that the electrically conductive substance is in the form of a gel. However, non-invasive imaging techniques (such as MRI, ultrasound, etc.) for guiding needles as well as chemotherapeutic fluids in the form of a gel are extremely well known in the art. Specifically, Mulier et al. teaches the use of "ultrasound guidance" of the needle **206** during the medical procedure (column 18, lines 25-43). In addition, Roskos et al. teaches the use of a chemotherapeutic fluid, such as cisplatin, in the form of "gel formulations for direct injections into a neoplastic lesion or surrounding tissue" (Abstract).

Thus, it would be obvious to one with ordinary skill in the art to use a non-invasive imaging technique, such as ultrasound guidance, for the purpose of reducing trauma due to invasive guidance procedures, as taught by Mulier et al., as well as a

chemotherapeutic fluid in the form of a gel suspension for treating the lesion, for the purpose of effectively treating the target area of a lesion, as taught by Roskos et al.

Regarding **claim 10**, Edwards et al. as modified discloses that as applied to **claim 1** as well as a needle apparatus that includes a biopsy needle guide through which the hollow core needle is inserted and the hollow core needle functions as the RF electrode (columns 13, 15, 16, etc.).

Regarding **claim 15**, Edwards et al. as modified discloses that as applied to **claim 1** as well as the use of imaging contrasting agents (column 17, lines 1-4). Therefore, it is within the scope of the modification to use imaging contrast agents for use in determining the volume of tissue penetrated.

Regarding **claim 17**, Edwards et al. as modified discloses that as applied to **claim 1** as well as necrosing agents and the use of RF (column 10, lines 55-58 and column 11).

Regarding **claim 21**, Edwards et al. as modified discloses that as applied to **claim 1** as well as a target tissue that is in a prostate and wherein the method is for treating a condition selected from the group of BPH and prostate cancer and is accomplished by a method selected from the group of transrectal, transurethral and transperineal approach (column 6, lines 60-63 and 08/148,441 which is incorporated by reference in column 1, line 11 (a copy has been previously provided)).

Regarding **claim 24**, Edwards et al. as modified discloses that as applied to **claim 1** as well as the method applied for treatment of a body part selected from the group of prostate, liver, uterus, bladder, kidney, lung and breast (column 4, line 14).

Regarding **claim 25**, Edwards et al. as modified discloses that as applied to **claim 24** as well as inserting that is accomplished using an approach selected form the group of percutaneous, laparoscopic, and endoscopic (column 6, lines 55-65).

Regarding **claim 30**, Edwards et al. as modified discloses that as applied to **claim 1** as well as guiding that is further performed using a device selected from the group of biopsy apparatus, laparoscope, endoscope, hysteroscope, MRI, CT scan, and ultrasound imaging apparatus (column 6, lines 55-65).

Regarding **claim 33**, Edwards et al. as modified discloses that as applied to **claim 1** as well as inserting that is performed by at least one method selected from the group of percutaneous, through incision, and through a natural body opening, and a laparoscopic approach, as stated throughout the specification.

Regarding **claim 37**, Edwards et al. as modified discloses that as applied to **claim 1** as well as chemotherapeutic agents such as tissue necrosing agents (column 11). Further, binding agents would be obvious if not inherent.

Regarding **claim 40**, Edwards et al. as modified discloses that as applied to **claim 1**. However, Edwards et al. do not explicitly recite a treatment substance having a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil. On the other hand, Roskos et al. teaches a treatment substance that is in the form of a gel suspension, wherein the gel suspension further has a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and

oil, as stated throughout specification. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Edwards et al. to use a gel suspension for the purpose of increasing viscosity allowing more controlled delivery, as taught by Roskos et al.

Regarding **claim 41**, Edwards et al. as modified discloses that as applied to **claim 1** as well as a conductive component that is selected from the group consisting of conductive polymers, conductive agents, conductive elements, conductive particles and metallic suspensions (column 16, line 16).

Regarding **claim 43**, Edwards et al. discloses a method for treating a localized portion of body tissue via inserting a needle apparatus in a body, the apparatus including at least one hollow needle core for delivering an electrically conductive substance into the body in the form of a chemotherapeutic fluid, whereby the substance is limited to a localized portion of body tissue (column 7, lines 45-55; column 8, lines 55-65; column 9, lines 22-25; column 10, lines 1-15; column 13; column 16; column 17, lines 1-5; and column 18, lines 5-13). Further, Applicant is directed to column 16, lines 15-20 where the electrically conductive solution is discussed. Further, Edwards et al. recites guiding the needle apparatus to a desired volume tissue in need of treatment (column 6, lines 55-65 and column 7, lines 50-55), applying the substance to the volume of tissue through the needle apparatus, determining that the volume of tissue is penetrated by the substance (as discussed throughout the disclosure), and applying RF energy to the substance through an RF electrode to ablate the volume of tissue, where

the substance serves an electrode extension conducting the RF energy throughout the volume (as recited throughout the disclosure with emphasis on columns 15-16).

However, Edwards et al. do not explicitly recite a non-invasive imaging technique for guiding the needle or that the electrically conductive substance is conveyed in a non-metallic, bio-absorbable microsphere container, such as a gel suspension. However, non-invasive imaging techniques (such as MRI, ultrasound, etc.) for guiding needles as well as chemotherapeutic fluids in the form of a gel suspension are extremely well known in the art. Specifically, Mulier et al. teaches the use of "ultrasound guidance" of the needle **206** during the medical procedure (column 18, lines 25-43). In addition, Roskos et al. teaches the use of a chemotherapeutic fluid, such as cisplatin, in the form of "gel formulations for direct injections into a neoplastic lesion or surrounding tissue" (Abstract), which are non-metallic, bio-absorbable materials fully capable of containing the microsphere containers of Edwards et al.

Thus, it would be obvious to one with ordinary skill in the art to use a non-invasive imaging technique, such as ultrasound guidance, for the purpose of reducing trauma due to invasive guidance procedures, as taught by Mulier et al., as well as a chemotherapeutic fluid in the form of a gel suspension for treating the lesion, for the purpose of effectively treating the target area of a lesion, as taught by Roskos et al.

Regarding **claim 20**, Edwards et al. as modified discloses that as applied to **claim 43**. Edwards et al. recites the use of microspheres in column 16. Therefore, it would be obvious and within the scope of the invention to also use microspheres in a gel suspension for the conductive solution. Thus, it is within the scope of the invention

and obvious to one with ordinary skill in the art to use microspheres (in a gel suspension) for providing image enhancement when the imaging technique is ultrasound (column 16 and column 17, lines 1-5).

Regarding **claim 38**, Edwards et al. as modified discloses that as applied to **claim 43** as well as microspheres that have a gas (some air inclusion is inherent). However, the solution of Edwards et al. is comprised of microspheres (column 16). Therefore, it would be obvious and within the scope of the invention to also use microspheres (in a gel suspension) for the conductive solution.

Regarding **claim 39**, Edwards et al. as modified discloses that as applied to **claim 38** as well as a gas that is selected form the group of air, helium, fluorocarbon, and carbon dioxide.

Regarding **claim 42**, Edwards et al. as modified disclosed that as applied to **claim 43**. Roskos et al. teaches the use of a chemotherapeutic fluid, such as cisplatin, in the form of "gel formulations for direct injections into a neoplastic lesion or surrounding tissue" (Abstract), which are non-metallic, bio-absorbable materials fully capable of being contained within the microsphere containers of Edwards et al. (as well as the other way around, i.e. the gel suspension containing microsphere containers). This modification would necessarily include the conductive gel within a biodegradable container, wherein biodegradable containers are discussed in column 16, lines 47-50 of the prior art specification of Edwards et al.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. **Claims 1, 10, 15, 17, 20, 21, 24, 25, 30, 33** and **37-43** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-78 of copending Application No. 10/193,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose apparatuses and methods inherent in the use of the apparatuses for treating portions of a body.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR
May 31, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700